IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: AVANDIA MARKETING, SALES : MDL NO. 1871 PRACTICES AND PRODUCTS : 07-MD-01871

LIABILITY LITIGATION

HON, CYNTHIA M, RUFE

THIS DOCUMENT APPLIES TO: : CIVIL ACTION

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Gerald Rowley v. GlaxoSmithKline, LLC No. 10-5934 Samuel Ascioti v. GlaxoSmithKline, LLC No. 10-6128 Jimmy Arflin v. GlaxoSmithKline, LLC No. 10-6129 George Belcher v. GlaxoSmithKline, LLC No. 10-6130 Diane Blount v. GlaxoSmithKline, LLC No. 10-6131 George Bowlin, Jr. v. GlaxoSmithKline, LLC No. 10-6132 Tim King v. GlaxoSmithKline, LLC No. 10-6135 Donald Lewis v. GlaxoSmithKline, LLC No. 10-6137 Clyde Pischner v. GlaxoSmithKline, LLC No. 10-6142 Daniel Rosebaro v. GlaxoSmithKline, LLC No. 10-6143 Gregory Vermilyea v. GlaxoSmithKline, LLC No. 10-6144 Paul Wyatt, II v. GlaxoSmithKline, LLC No. 10-6146 Aniello Murano v. GlaxoSmithKline, LLC No. 10-6147 Calvin Day v. GlaxoSmithKline, LLC No. 10-7473 Amjad Faheem v. GlaxoSmithKline, LLC No. 11-695 Jimmy Dunn v. GlaxoSmithKline, LLC No. 11-696 William Doss v. GlaxoSmithKline, LLC No. 11-697 Mary Diaz v. GlaxoSmithKline, LLC No. 11-699 Marvin Dean v. GlaxoSmithKline, LLC No. 11-700 Francesco D'Amico, Jr. v. GlaxoSmithKline, LLC No. 11-704 William Cottrell v. GlaxoSmithKline, LLC No. 11-706 John Cohen v. GlaxoSmithKline, LLC No. 11-708 Rand Briem v. GlaxoSmithKline, LLC No. 11-709 Donna Brazzell v. GlaxoSmithKline, LLC No. 11-710 Terry Borton v. GlaxoSmithKline, LLC No. 11-711 Wilfred Bretrand v. GlaxoSmithKline, LLC No. 11-712 Thomas Battle v. GlaxoSmithKline, LLC No. 11-713 Esther Tharp v. GlaxoSmithKline, LLC No. 11-714 Monica Puthumana v. GlaxoSmithKline, LLC No. 11-715 Jose Patino v. GlaxoSmithKline, LLC No. 11-716 Glenn Patin v. GlaxoSmithKline, LLC No. 11-717 Douglas Moseley v. GlaxoSmithKline, LLC No. 11-718 Jerry Morris v. GlaxoSmithKline, LLC No. 11-719 Jerry Mize v. GlaxoSmithKline, LLC No. 11-720

Ismael Medrano, Sr. v. GlaxoSmithKline, LLC	:	No. 11-721
John McCusker, Sr. v. GlaxoSmithKline, LLC	:	No. 11-722
Delores Leflore v. GlaxoSmithKline, LLC	:	No. 11-723
David Lawter v. GlaxoSmithKline, LLC	:	No. 11-724
James Lancaster, Jr. v. GlaxoSmithKline, LLC	:	No. 11-725
Leo Jordan v. GlaxoSmithKline, LLC	:	No. 11-726
Marcelean Jones v. GlaxoSmithKline, LLC	:	No. 11-727
Deloris Jackson v. GlaxoSmithKline, LLC	:	No. 11-729
Charles Head v. GlaxoSmithKline, LLC	:	No. 11-730
Harriet Green v. GlaxoSmithKline, LLC	:	No. 11-731
Peter J. Garlock v. GlaxoSmithKline, LLC	:	No. 11-732
Albert Wooldridge v. GlaxoSmithKline, LLC	:	No. 11-733
Kerry Wilson v. GlaxoSmithKline, LLC	:	No. 11-734
Barbara Wilson v. GlaxoSmithKline, LLC	:	No. 11-735
Pamela Ward v. GlaxoSmithKline, LLC	:	No. 11-736
Donna Tucker v. GlaxoSmithKline, LLC	:	No. 11-737
Jack Summey v. GlaxoSmithKline, LLC	:	No. 11-738
Fred Stewart v. GlaxoSmithKline, LLC	:	No. 11-739
Daniel Southerland v. GlaxoSmithKline, LLC	:	No. 11-740
Thomas Smith v. GlaxoSmithKline, LLC	:	No. 11-741
Gerald Sipplen v. GlaxoSmithKline, LLC	:	No. 11-742
Alan Simzyk v. GlaxoSmithKline, LLC		No. 11-743
Robert Scott v. GlaxoSmithKline, LLC	:	No. 11-744
Rosemary Savedge v. GlaxoSmithKline, LLC	:	No. 11-745
Paula Winter v. GlaxoSmithKline, LLC	:	No. 11-746
David Magidson v. GlaxoSmithKline, LLC	:	No. 11-938

MEMORANDUM OPINION AND ORDER

Rufe, J. September 7, 2011

The plaintiffs in these 60 cases filed suit alleging that they (or their decedents) suffered injuries (including strokes, congestive heart failure, and myocardial infarcations) caused by their ingestion of the drug Avandia. Defendant, GlaxoSmithKline, LLC ("GSK"), contends that Plaintiffs' claims are barred by the applicable statutes of limitations.

I. LEGAL STANDARD

GSK has moved to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), or in the alternative, for judgment on the pleadings pursuant to Rule 12(c). In the Third Circuit, a limitations defense may be raised by a motion under Rule 12(b)(6), but only if "the time alleged in the statement of a claim shows that the cause of action has not been brought within the statute of limitations." "If the bar is not apparent on the face of the complaint, then it may not afford the basis for a dismissal of the complaint under Rule 12(b)(6)." The same standard also applies to motions for judgment on the pleadings filed pursuant to Rule 12(c).

II. DISCUSSION

All of these cases were filed directly in this Court as tag-along actions to the Multi-District Litigation proceedings, but the plaintiffs reside throughout the country. GSK argues that under these circumstances, Pennsylvania law applies with regard to the appropriate statute of limitations, and Plaintiffs, without conceding that Pennsylvania law should apply, have cited to Pennsylvania law as well. Because it does not appear that the outcome would be different if other laws were applied, and the motions are based upon general principles rather than circumstances specific to individual Plaintiffs, the Court will determine the motions under

¹ <u>Hanna v. U.S. Veterans' Admin. Hosp.</u>, 514 F.2d 1092, 1094 (3d Cir. 1975), <u>quoted in Robinson v.</u> <u>Johnson</u>, 313 F.3d 128, 135 (3d Cir. 2002).

² Bethel v. Jendoco. Constr. Corp., 570 F.2d 1168, 1174 (3d Cir. 1978).

³ See <u>Turbe v. Gov't of the Virgin Islands</u>, 938 F.2d 427, 428 (3d Cir. 1991).

Pennsylvania law.⁴ The Court recognizes that there is a question as to the law that should govern cases filed directly in the MDL by plaintiffs from states other than Pennsylvania but will reserve for another day the resolution of this issue.⁵

The Pennsylvania statute of limitations for personal injury and wrongful death claims is two years.⁶ Although the statute of limitations ordinarily begins to run at the time the plaintiff sustains an injury,⁷ Pennsylvania courts recognize the "discovery rule," whereby the statute of limitations does not begin to run until the plaintiff knows or reasonably should know that she has been injured and that her injury has been caused by another party's conduct.⁸ To take advantage of the discovery rule, the plaintiff must exercise reasonable diligence, which is "a reasonable effort to discover the cause of an injury under the facts and circumstances present in the case." There must be some reason to awaken inquiry, and the standard of reasonable diligence is an objective, not a subjective, one under which "the plaintiff's actions must be evaluated to determine whether he exhibited those qualities of attention, knowledge, intelligence and

⁴ Two Plaintiffs are from Pennsylvania, so Pennsylvania law certainly applies to those Plaintiffs.

⁵ See, e.g., In re Yasmin and Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig., No. 3:09-MD-2100, 2011 WL 1375011, *5 (S.D. Ill. Apr. 12, 2011) (holding that cases that originated outside of the court's judicial district and that were filed directly into the MDL would be treated as if they were transferred from a judicial district sitting in the state where the case originated).

⁶ 42 Pa. Cons. Stat. § 5524. Pennsylvania also has a "borrowing statute" which provides that "[t]he period of limitation applicable to a claim accruing outside this Commonwealth shall be either that provided or prescribed by the law of the place where the claim accrued or by the law of this Commonwealth, whichever first bars the claim." 42 Pa. Cons. Stat. Ann. § 5521(b). Pursuant to this statute, the one-year limitations periods of Kentucky, Louisiana, and Tennessee would apply to the claims of the plaintiffs from those states. Def. Mem. at 10 n.3. Because the shorter limitations period does not affect the resolution of these motions, it will not be discussed further.

⁷ <u>Debiec v. Cabot Corp.</u>, 352 F.3d 117, 129 (3d Cir. 2003).

⁸ Id. (citing Cathcart v. Keene Indus. Insulation, 471 A.2d 493, 500 (Pa. Super. Ct. 1984)).

⁹ Cochran v. GAF Corp., 666 A.2d 245, 249 (Pa. 1995).

judgment which society requires of its members for the protection of their own interests and the interests of others."¹⁰ The question of reasonable diligence is usually for the jury unless "the facts are so clear that reasonable minds cannot differ."¹¹ GSK argues that beginning on May 21, 2007, the facts were clear enough to awaken the plaintiffs' duty of inquiry.

In moving for dismissal based on the statute of limitations, GSK relies upon the allegations of the complaint and media coverage of Avandia. GSK refers to the following allegations of the complaints:

- 54. Following the May 21, 2007 NEJM publication of the Nissen/Wolski metaanalysis, the FDA issued a safety alert for Avandia and advised patients who take it to consult their doctors.
- 55. On June 1, 2007, Defendant published a "Dear Avandia Patient" letter, which responded to the "recent press coverage about the safety of Avandia." Therein, Defendant stated that it "stands firmly behind Avandia" and that "Avandia is the most widely studied medicine for type II diabetes" and that the evaluation of clinical trials by "well-informed experts and researcher [sic] has been encouraging."
- 56. At the congressional hearing on June 6, 2007, the FDA indicated that a black box warning should be added to rosiglitazone (Avandia), for increased risk of heart failure.
- 57. On July 30, 2007, the FDA held an Advisory Committee Hearing on the safety of Avandia. The panel was determining whether to recommend keeping the label the same, adding a black box warning, or taking Avandia off the market all together.
- 60. The panel of advisers to the Food and Drug Administration voted 20-to-3 that Avandia increases the risks of heart attacks.¹²

¹⁰ <u>Id.</u> at 250 (internal quotation omitted).

¹¹ Id. at 248.

 $^{^{12}}$ Battle Am. Compl. ¶¶ 54-57, 60. All of the complaints include the same or similar allegations.

Relevant to the motions to dismiss, the complaints also allege that:

- 61. Despite knowing of this defect [the alleged increased risks of heart attacks] prior to the date of Plaintiff's injury due to the use of Avandia, Avandaryl and/or Avandamet, the Defendant took inadequate steps to advise physicians, hospitals, nursing homes and other health care providers of the possibility of heart attacks, cardiovascular injury, cerebrovascular accidents and death.
- 62. Despite having actual notice of the dangerous propensities associated with Avandia, Avandaryl and/or Avandamet, prior to the date Plaintiff purchased and used Avandia, Defendant took inadequate steps to advise consumers or medical providers, including Plaintiff of the known dangers of Avandia, Avandaryl and/or Avandamet consumption, including but not limited to the increased risk of heart attacks, cardiovascular injury, cerebrovascular accidents and deaths. Defendant failed to take adequate steps to ensure that the Avandia, Avandaryl and/or Avandamet it manufactured was safe for the public and would function in the manner in which they were intending.

. . .

64. Even after being made aware of the numerous reports of myocardial infarctions, including those adverse events that occurred during Defendant's own studies, Defendant still failed to take all reasonable and necessary steps to ensure that the consuming public, including Plaintiff, was aware of the increased risk of suffering a heart attack, cardiovascular injury, cerebrovascular accidents, or death. As stated in above [sic], Defendant knew that Avandia, Avandaryl and/or Avandamet caused heart attacks, cardiovascular injury, cerebrovascular accidents, and deaths.¹³

The plaintiffs also allege that they "did not know, nor should have known" that their injuries were allegedly caused by Avandia until "late summer 2010" and "did not see any information" about the risks of injury before that time.¹⁴ Considering all of these allegations, the Court cannot determine that the affirmative defense of the statute of limitations is clear on the face of the

¹³ <u>Id.</u> ¶¶ 61-62, 64.

¹⁴ <u>Id.</u> ¶¶ 77-79.

complaints.15

In addition to the allegations in the complaints, GSK argues that a "storm of media attention about Avandia in May-November 2007" should have put the plaintiffs on notice to investigate the cause of their injuries. The Court will take judicial notice of the newspaper articles, to the extent that they "indicate what was in the public realm at the time, not whether the contents of those articles were in fact true." The articles do not, however, establish as a matter of law that the plaintiffs were required at that time to investigate a possible link between Avandia and their injuries. First, it is not known whether any of the plaintiffs were taking Avandia during mid-2007; if they were not, it is not reasonable to assume that they would notice any articles about Avandia. Second, many of the cited articles note that the FDA was not recommending that Avandia be withdrawn from the market, and the articles do not mention some health conditions now allegedly associated with Avandia. Third, the articles cannot be considered in a vacuum. Because there has been no discovery, there is no evidence, for example, as to whether the plaintiffs questioned their doctors as to the cause of their injuries, or what their doctors told them; nor is there evidence more generally as to what information prescribing physicians had at

¹⁵ GSK argues that the allegations that plaintiffs were unaware of the potential connection of Avandia to their injuries until 2010 lack specificity and should be disregarded. The Court disagrees that the plaintiffs are required to plead more about what they did not know. "It is true that the party seeking to benefit from the discovery rule has the burden of establishing its inability to know of the injury despite the exercise of reasonable diligence. However, a plaintiff has no obligation to anticipate a statute of limitations affirmative defense and, therefore, has no obligation to plead facts pertaining to reasonable diligence. If there are insufficient facts in the pleadings to conclusively determine whether the 'discovery rule' exception applies, the motion to dismiss must be denied." Farm Credit Leasing Servs. Corp. v. Ferguson Packaging Mach., Inc., No. 07-CV-1900, 2007 WL 4276841, *5 n.3 (E.D. Pa. Dec. 3, 2007) (internal citation omitted).

¹⁶ GSK Mem. at 13.

¹⁷ Benak ex rel. Alliance Premier Growth Fund v. Alliance Capital Management L.P., 435 F.3d 396, 401 n.15 (3d Cir. 2006).

that a study raising questions about the safety of Avandia in mid-2007 started the limitations clock.¹⁹ There is certainly a point at which a reasonable person was on notice to investigate the possibility of a connection between an injury and use of Avandia, but the Court cannot, on the present record, determine that point to be May 21, 2007.²⁰ The motions to dismiss will be denied.²¹ An appropriate order will be entered.

¹⁸ Martin v. Dalkon Shield Claimants Trust, 1994 WL 649248, *4 (E.D. Pa. Nov. 16, 1994).

In other drug cases, the courts have held that plaintiffs were put on notice by extensive publicity that accompanied the withdrawal of the drugs from the market. For example, in the diet drugs litigation, the Court of Appeals for the Third Circuit held that the plaintiffs were on notice, at the latest, after a notification campaign in connection with a class-action settlement, which was after the withdrawal of the drugs from the market. In re Briscoe, 448 F.3d 201, 220-21 (3d Cir. 2006) (denying mandamus relief). In the Vioxx litigation, In re Vioxx Prods. Liab. Litig., 522 F. Supp. 2d 799, 801 (E.D. La. 2007), the court, ruling in the context of a renewed motion for summary judgment, noted that Merck voluntarily withdrew Vioxx from the market on September 30, 2004, and issued a public letter to patients informing them of the risks associated with Vioxx. Id. at 802. "The withdrawal of Vioxx from the market was arguably the largest and most-publicized prescription drug withdrawal in this country's history." Id. at 803. Therefore, the court determined that at the latest, the statute of limitations began to run on September 30, 2004.

At oral argument on the motions, counsel for Avandia stated that "[t]he only date I'm arguing for is May 21, 2007." Tr. Aug. 8, 2011 at 117. At the same argument, Plaintiffs' counsel acknowledged that by the time a Risk Evaluation and Mitigation Strategy for Avandia was instituted in September 2010, restricting the drug's availability, a plaintiff would be hard-pressed to argue that she was not on notice of a possible link between Avandia and injury. Id. at 146.

²¹ In 13 of the cases, GSK also argued for dismissal for failure to state a claim upon which relief can be granted; those arguments have been withdrawn.